newdeal®
An Integra LifeSciences Company

K071639 pg 1 of 2

510(k) SUMMARY

JUL - 9 2007

A. **Submitter's Name and Address:**

Newdeal SAS
10, place d'Helvétie
69006 LYON
FRANCE
Tel.: +33 4 37 47 51 51
Fax: +33 4 37 47 51 52
ESTABLISHMENT REGISTRATION NUMBER: 9615741

B. **Contact Person:**

Morgane GRENIER
Director of Regulatory and Clinical Affairs
Newdeal SAS
10, place d'Helvétie
69006 LYON
FRANCE
Tel: +33 4 37 47 51 51
Fax: + 33 4 37 47 51 52

C. **Date Summary Prepared:**
June 13, 2007

D. **Name of Device:**
Proprietary Name: QWIX® Positioning Screw

Common Name: Bone fixation screw

Classification Name and Reference:
Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Device Product Code: HWC

Proposed Regulatory Class: Class II

Panel: Orthopedic

E. **Device Description**
The QWIX® Positioning Screw is a cannulated fully threaded screw. It also has a self-tapping screw tip. It is provided in diameters 5.5 mm and 7.5 mm and in length from 30 mm to 80 mm for the 5.5 mm and from 40 mm to 120 mm for the 7.5 m. The **QWIX® Positioning Screw** is made from Titanium alloy (Ti-6Al-4V ELI).

F. Indications for Use

The **QWIX® Positioning Screw** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-cortical osteotomies in the foot or hand
- Hallux Valgus treatment
- Fractures management in the foot or hand
- Fixation of bone fragments in long bones or small bones fractures
- Arthrodesis in hand, foot or ankle surgery

The size of the chosen screw should be adapted to the specific indication.

G. Substantial Equivalence

The QWIX® Positioning Screw is substantially equivalent to commercially marketed device, Stabilization Screw, K050346.

H. Comparison of Technological Characteristics

The modified device has the same fundamental scientific technology and intended uses as the predicate device.

The modified screw has the following similarities to those which previously received 510(k) concurrence:

- Same intended use
- Same materials
- Same basic design
- Same Instructions for Use
- Same manufacturing process

I. Summary of Studies

Mechanical tests have been carried out. Results have shown that the mechanical properties of the QWIX® Positioning Screw staples have similar to properties of predicate devices, such as Newdeal ICOS screws (K011821) and Synthes 7.3 screw (K962011).

J. Conclusion

The new QWIX® Positioning Screws are substantially equivalent to the commercially marketed device, Stabilization Screw, K050346.

The modifications do not change the intended use or fundamental scientific technology of the device and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2007

Integra LifeSciences Corporation
% Ms. Judith E. O'Grady
Senior VP, Regulatory, Quality & Clinical Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K071639
Trade/Device Name: QWIX® Positioning Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 14, 2007
Received: June 15, 2007

Dear Ms. O'Grady:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Boyer for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071639

Device Name: **QWIX Positioning Screw**

Indications For Use:

The **QWIX Positioning Screw** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Mono or Bi-cortical osteotomies in the foot or hand (including Hallux Valgus treatment)
- Fractures management in the foot or hand
- Fixation of bone fragments in long bones or small bones fractures
- Arthrodesis in hand, foot or ankle surgery

The size of the chosen screw should be adapted to the specific indication.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brochman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071639